

12 HOUR DECONGESTANT- pseudoephedrine hydrochloride tablet, film coated, extended release

L Perrigo Company

Perrigo 12 Hour Decongestant Drug Facts

Active ingredient (in each tablet)

Pseudoephedrine HCl 120 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves sinus congestion and pressure

Warnings

Do not use

if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

When using this product

do not exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with a fever

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

adults and children 12 years and over	<ul style="list-style-type: none"> • take 1 tablet every 12 hours • do not take more than 2 tablets in 24 hours
children under 12 years	do not use this product in children under 12 years of age

Other information

- each tablet contains: calcium 45 mg
- store at 20° - 25°C (68° - 77°F) in a dry place
- protect from light
- do not use if blister unit is broken or torn
- see carton end panel for lot number and expiration date
- this product meets the requirements of USP Drug Release Test 3

Inactive ingredients

carnauba wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

Sinus

Non-Drowsy

Compare to Sudafed® 12 Hour Caplets active ingredient

12 Hour

Decongestant

Pseudoephedrine Hydrochloride Extended Release Tablets 120 mg

Long-Acting Nasal Decongestant

Sinus Pressure

Congestion

Maximum Strength

Pseudoephedrine HCl

(120 mg each)

*(capsule-shaped tablets)



Non-Drowsy

12 Hour Decongestant

Pseudoephedrine Hydrochloride Extended Release Tablets 120 mg
Long-Acting Nasal Decongestant

NDC 0113-2054-60

Sinus

Non-Drowsy

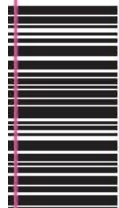
*Compare to Sudafed®
12 Hour Caplets
active ingredient*

12 Hour Decongestant

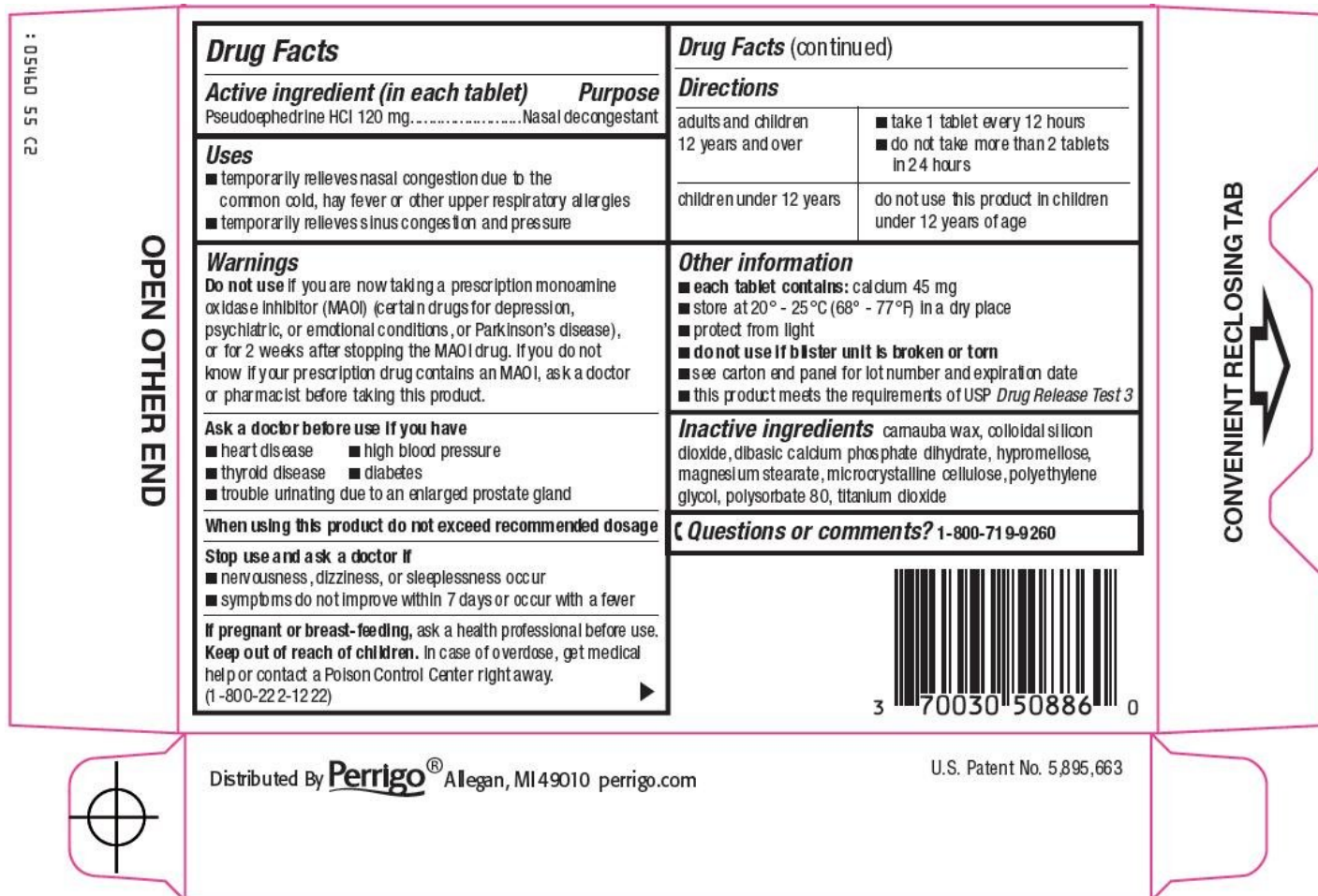
Pseudoephedrine Hydrochloride
Extended Release Tablets 120 mg
Long-Acting Nasal Decongestant

- Sinus Pressure • Congestion
- Maximum Strength
- Pseudoephedrine HCl

20 COATED CAPLETS*
(120 mg each) *capsule-shaped
tablets



12 Hour Decongestant Carton Image 1



12 Hour Decongestant Carton Image 2

12 HOUR DECONGESTANT

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0 113-2054
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDOEPHEDRINE - UNII: 7CUC9DDI9 F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	WHITE	Score	no score	
Shape	CAPSULE	Size	18mm	
Flavor		Imprint Code	L054	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0113-2054-60	2 in 1 CARTON		
1		10 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA075153		10/04/2011	

Labeler - L Perrigo Company (006013346)

Revised: 3/2012

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